

Notice of Allowability**Application No.**

10/086,641

Examiner

Elliot L Frank

Applicant(s)

BLOMQUIST, MICHAEL L.

Art Unit

2125

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendment filed 9 July 2004.
2. ☒ The allowed claim(s) is/are 1-23.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date 6 January 2004.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

- ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance:
 - a. The prior art of record, taken singly or in any reasonable combination fails to teach or fairly suggest the claimed invention.
 - b. Independent claim 1 (and functionally similar claim 6) requires the following:
 1. A method of delivering a bolus from a pump, the pump being a programmable medical infusion pump having a keypad, the method comprising:

programming a bolus amount into the pump; programming a duration into the pump;

programming a percentage into the pump, the percentage defining a portion of the bolus amount to deliver immediately upon executing a deliver command and a remainder of the bolus amount to deliver over the duration upon executing a deliver command; and

executing the deliver command.
 - c. Independent claim 10 (and functionally similar claim 17) require the following:
 10. A method of temporarily adjusting the delivery rate of an infusion pump, the infusion pump programmed to deliver a basal rate, the method comprising:

prompting a user to select whether to enter the temporary rate as a percent of the current delivery rate or as a new delivery rate;

entering into the pump a period of time having a beginning and an end;
entering into the pump a temporary basal rate; and
delivering the therapeutic agent at a delivery rate substantially equal to the temporary basal rate during the period of time.

- d. Bylund et al. (US 2003/0212379 A1) is the most relevant prior art of record.

While Bylund et al. anticipates an insulin delivery system that may be programmed to deliver an immediate bolus amount and an extended bolus amount over a period of time, the applicant has pointed out that the instant invention claims a non-obvious improvement over the prior art of record wherein the bolus proportions are entered via a single percentage rather than an bolus amount to be immediately delivered and a bolus amount to be subsequently delivered over an extended time as in the prior art. The basal rate in the instant invention is also controlled via a single percentage of the standard delivered amount per claim 10. Additional focused searching on these percentage limitations has not uncovered any additional references that would anticipate nor even suggest this implementation of drug delivery control. As a result, the examiner has rescinded the previously presented obviousness rejection.

- e. Therefore, the limitations of the independent claims, in combination with the remaining elements and features of the claimed invention, was not disclosed nor fairly suggested by the prior art of record.

2. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elliot L Frank whose telephone number is (571) 272-3739. The examiner can normally be reached on M-F 8-5:00 (flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo P Picard can be reached on (571) 373-3749. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ELF – 12 September 2004



LEO PICARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2100

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